



RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1642

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S-1203

PATENT
Attorney Docket No. 218791
Client Reference No. E-265-1997/0-US-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wang et al.

Application No. 09/529,206

Filed: June 13, 2000

For: NOVEL HUMAN CANCER ANTIGEN
NY ESO-1/CAG-3 AND GENE
ENCODING THE SAME

Art Unit: 1642

Examiner: M. Yu

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RESPONSE TO FINAL OFFICE ACTION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the final Office Action dated March 4, 2003, please consider the following remarks.

REMARKS

The Present Invention

The present invention pertains to cancer peptides consisting essentially of amino acids 55-62 of SEQ ID NO: 4 or amino acids 127-136 of SEQ ID NO: 4 or a functionally equivalent variant thereof, as well as compositions and immunogens, both of which comprise the cancer peptides.

The Pending Claims

Claims 3, 5-8, 10-16, 26, 28, 29 and 67-86 are currently pending, of which claims 3, 5-8, 10-16 and 67-77 are directed to cancer peptides, claims 26 and 86 are directed to compositions comprising the cancer peptides, and claims 28, 29 and 78-85 are directed to immunogens comprising the cancer peptides.

The Final Office Action

The Office has maintained the restriction requirement imposed in Paper No. 20 and alleges that claims 10-16 are drawn to non-elected species and remain withdrawn from further consideration. The Office also maintains the rejection of claims 3, 5-8, and 26 under 35 U.S.C. § 102 for allegedly being anticipated by Chen et al., *Proc. Natl. Acad. Sci. USA* 94: 1914-1918 (1997). The Office has rejected claims 3, 5-8, 26, 28, 29, and 67-86 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. Reconsideration of the withdrawal of claims 10-16 and of these rejections is hereby requested.

Discussion of the Restriction Requirement

The Office has maintained the restriction requirement imposed in Paper No. 15, since the species allegedly have "different molecular formula[e] with different biological activities" (page 2 of Paper No. 24). The Office further contends that Applicants elected with traverse claims 1-30 drawn to cancer peptides with species C (SEQ ID NO: 4). The Office claims that the election, treated as without traverse, reads on claims 3, 5-8, 26, and 27. According to the Office, claims 10-16 are drawn to non-elected species and remain withdrawn from further consideration. However, as *all* of the pending claims read on cancer peptides relating to the elected species SEQ ID NO: 4, claims 10-16 should not be withdrawn from further consideration. In fact, claims 10, 14, and 15 are similar to claims 74-77, such that it is improper to withdraw claims 10, 14, and 15 from prosecution when claims 74-77 remain in prosecution. Furthermore, claim 13 is similar to claim 69. It also would be improper to withdraw claim 13 from prosecution given that claim 69 remains in prosecution. Claim 16 should also remain in prosecution, since it is directed to a fragment of SEQ ID NO: 4 similarly to claim 3. In view of the fact that the Office has already considered claims 69 and 74-77, it would not be a burden for the Office to also consider claims 10-16. Therefore, Applicants request that claims 10-16 be considered by the Office and remain in prosecution.

Discussion of the Rejection under 35 U.S.C. 102(a)

The Office has maintained the rejection of claims 3, 5-8, 26, and 27 under Section 102(a) as allegedly anticipated by Chen et al., *Proc. Natl. Acad. Sci. USA* 94: 1914-1918 (1997). Specifically, the Office alleges that, because the claims recite "consisting essentially of," the peptides of the present invention are anticipated by Chen et al., which discloses the full-length amino acid sequence of NY ESO-1/CAG-3 (SEQ ID NO: 4). This rejection is traversed for the reasons set forth below.

The Office alleges that the transitional phrase "consisting essentially of" is the same as "comprising" and, since Chen et al. discloses SEQ ID NO: 4, the present invention is anticipated by Chen et al. However, the use of "consisting essentially of" is known to not have the same meaning as that of the term "comprising." See the Manual of Patent Examining Procedure (M.P.E.P.) at Section 2111.03. Furthermore, the specification defines the term "cancer peptides" at, for instance, page 9, lines 2-3. Specifically, it states that "[c]ancer peptides' as the term is used herein, encompasses any epitope or fragment of cancer or tumor protein, which acts as a tumor antigen." In the instant case, NY ESO-1/CAG-3 is the cancer or tumor protein of which the present inventive cancer peptides are fragments or epitopes. Moreover, since the specification discloses numerous cancer peptides at, for example, Table 7 on page 50, all of which consist of no more than 15 amino acids, it is clear to one of ordinary skill in the art that the present invention does not read on the full-length sequence of SEQ ID NO: 4, which, by contrast, is 180 amino acids in length. Therefore, Chen et al., which discloses only the full-length sequence of SEQ ID NO: 4 and not the specific regions of SEQ ID NO: 4 that are subject of the present patent application, does not disclose the present inventive cancer peptides.

In view of the foregoing, the present inventive peptides are not anticipated by Chen et al. Therefore, Applicants request that the rejection of claims 3, 5-8, 26, and 27 under Section 102(a) be withdrawn.

Discussion of Rejection under 35 U.S.C. § 112, first paragraph, written description

The Office has rejected claims 3, 5-8, 26, 28, 29, and 67-86 under Section 112, first paragraph, as allegedly lacking written description. Specifically, the Office contends that the specification does not communicate that the instant invention is a peptide consisting essentially of amino acids 55-62 of SEQ ID NO: 4 and concludes that this is new matter. This rejection is traversed for the reasons set forth below.

The present inventive cancer peptides are disclosed in the originally-filed specification at, for instance, Table 7 on page 50. In the Amendment and Response to Office Action filed on November 6, 2002, the claims were amended to demonstrate to the Office that all of the present inventive cancer peptides are unified by the fact that they are all structurally related to a single amino acid sequence, namely, SEQ ID NO: 4, which is the coding sequence of NY ESO-1/CAG-3. The cancer peptides, which are now described in terms of amino acid position numbers of SEQ ID NO: 4, consistent with the M.P.E.P. at Section 2423.03, are inherently supported by the originally-filed specification, since SEQ ID NO: 4 is found on page 9 and in Figures 3A-1 and 3A-2 and the position numbers used to

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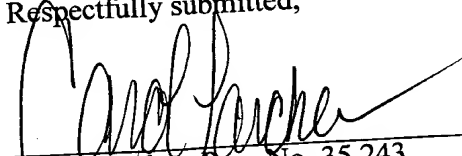
describe the present inventive cancer peptides correspond with the disclosed sequences found at each of these locations within the originally-filed specification. The Office is reminded of the M.P.E.P. at Section 2163.07 (a), which states that "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)." In view of the M.P.E.P., the fact that Applicants have chosen to claim the peptides by amino acid position with respect to SEQ ID NO: 4, instead of by reciting amino acid sequence, undoubtedly is supported by the specification and cannot be construed as new matter. The specification supports both methods of description. Therefore, as the originally-filed specification inherently supports the present inventive cancer peptide consisting essentially of amino acids 55-62 of SEQ ID NO: 4, the cancer peptides of the pending claims are not new matter.

In view of the foregoing, Applicants submit that the present invention is not new matter and meets the written description requirement of 35 U.S.C. Section 112, first paragraph. Therefore, Applicants request that the rejection be withdrawn.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,


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Date: May 5, 2003

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Appln. No.: 09/529,206

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO FINAL OFFICE ACTION (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: May 5, 2003

A handwritten signature in cursive script, appearing to read "Sherry Pay", is written over a horizontal line.

Date: May 5, 2003

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Corres. and Mail

BOX AF

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a Response to Final Office Action in the subject application.

☐ Applicants claim small entity status of this application under 37 CFR 1.27.

☒ Petition for Extension of Time
☐ Applicants petition for a one-month extension of time under 37 CFR 1.136, the fee for which is \$110.00 (enclosed).

☒ Applicants believe that no petition for an extension of time is necessary. However, to the extent that such petition is deemed necessary, Applicants hereby petition for a sufficient extension of time to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.

☒ No additional claim fee is required.

☐ Other:

The claim fee has been calculated as shown below:

| | | | | | SMALL ENTITY | | OTHER THAN A SMALL ENTITY | |
|--------------------------|--------------------------------------|-------|------------------------------------|----------------------|--------------|------------------|---------------------------|------------------|
| | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | EXTRA CLAIMS PRESENT | RATE | ADDIT. CLAIM FEE | RATE | ADDIT. CLAIM FEE |
| TOTAL | 35 | MINUS | 66 | =0 | x 9= | \$ | x 18= | \$0.00 |
| INDEPENDENT | 2 | MINUS | 16 | =0 | x 42= | \$ | x 84= | \$0.00 |
| <input type="checkbox"/> | FIRST PRESENTATION OF MULTIPLE CLAIM | | | | + 140= | \$ | + 280= | \$ |
| | | | | | TOTAL | \$ | TOTAL | \$0.00 |

☐ Please charge my Deposit Account No. 12-1216 in the amount of \$. A duplicate copy of this sheet is attached.

☐ A check in the amount of \$ is attached.

☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is attached.

☒ Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

☒ Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,
LEYDIG, VOIT & MAYER, LTD.

By

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